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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/280,279	03/29/1999	JON M. MILLER	MILLER.P001	5533
7590	11/04/2004			
DONALD L. COX LYNCH, COX, GILMAN & MAHAN AEGON CENTER- SUITE 2200 400 W. MARKET LOUISVILLE, KY 40202			EXAMINER SHARAREH, SHAHNAM J	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/280,279

Applicant(s)

MILLER, JON M.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 17, 2004 has been entered.

The effective filing date for this Application is March 29, 1999. Claims 29-39 are pending. The rejection under 35 USC 102(b) over Detusch is viewed to be obviated in view of the Amendments. The rejection of claims under 35 USC 103(a) over Rosenberg in view of Deutsch is moot in view of the new grounds of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-31, 33-37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritter US Patent 4,293,562.

Ritter administers cimetadine, an H<sub>2</sub> Antagonist, with an anorexant such as dextroamphetamine, phenteramine or phenmetrazine. Ritter uses this combination to suppress the appetite of a mammal as an adjunct to weight control. (abstract, col 4-6). The amphetamines used by Ritter are viewed to fall within the scope of the instant

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"mood altering" and "psychotropic agents" because they exert a central effect upon the mind or are able to modify mental activity of the patients who takes them. For example, Ritter clearly states that amphetamine can cause CNS stimulation (see col 1, lines 35-55; col 2, lines 34-36). Ritter also claims dosage forms that comprise both the cimetadine and the anorexant. (see claims 1,4,5). Ritter's patients are viewed to be in need of an anorexant because they are taking such drug during their course of treatment. Thus, Ritter anticipates all limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bymaster et al EP 0 830 864 in view of Deutsch et al (CNS Drugs, 1997, 8(4): 276-284) and Kaminiski US Patent 5,070,101 and Vivino US Patent 4,220,653.

Bymaster teaches various compositions containing compounds such as Olanzapine, Quetiapine, Risperidone that provide antipsychotic effects. (see page 8, lines 45-page 9, line20). Bymaster's compositions can be used to treat psychotic conditions such as schizophrenia, schizoaffective disorders, catonic type schizophrenia, etc.. (see page 12, lines 49, page 13, line10; claims 6-7). Bymaster does not teach the use of an H2-antagonist in his methods

Deutsch and Kaminiski teach that adding an H2-antagonist such as famotidine would improve positive and negative symptoms of schizophrenia. For example, Deutsch describes the therapeutic benefits of famotidine when used as an adjunct therapy for schizophrenia (see abstract, page 277, col 2-page 279; page 282-2<sup>nd</sup> col-page 283).

Kaminiski substantiates the teachings of Deutsch and further states that famotidine improves the negative symptoms of schizophrenia (see abstract, col 3-4). Kaminiski also adds that other H2-antagonists can be useful for treatment of schizophrenia (see col 4, lines 21-35).

Bymaster's Deutsch and Kaminiski do not explicitly recite that that H2-antagonists can also be used for purposes of weight control and weight loss.

Vivino describes the state of art that H2-antagnoists such as cimetidine are used for persons suffering from excessive weight as a mode to reduce the feelings of hunger and food intake. (see abstract, col 4, lines 1-44). Thus, Vivino suggests that H2-antagonists such as cimetidine are effective for suppressing appetite.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to also use H2-antagnoists such as cimetidine or famotidine in

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combination with antipsychotics of Bymaster to further reduce appetite and help patient's weight control. Moreover, formulating a composition to contain such ingredients would have also been well within the purview of the ordinary skill in the art.

The ordinary skill in the art would have been motivated to use H2-antagonists with the antipsychotic regimens of Bymaster, because as described by Deutsch and Kaminiski, H2-antagonists are expected to improve schizophrenic symptoms. Therefore, employing weight control benefits of H2-antagonists as described by Vivino would have also been obvious, because the ordinary skill in the art would have had a reasonable expectation of success to observe all therapeutic benefits of such drugs including its appetite reducing effects in the recipient patients.

One of ordinary skill in the art would have further been motivated to formulate a single dosage form containing the psychotropic and H2-antagonists of choice, because the ordinary skill in the art would have had a reasonable expectation of success to improve patient compliance with a single dosage form.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RUSSELL TRAVERS  
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